

REMARKS

Claims 1-3, 5-12 and 21-28 are in this application and are presented for reconsideration. By this amendment, Applicant has made minor changes to claims 23 and 25. The changes are a minor clarification. It is believed that no new issues are raised by the change as the claim was being considered in a manner which is consistent with the clarified text. It is believed that the clarified text makes the claim clearer and that this is necessary now based on applicant's attorney's review of the claims. Entry of this amendment is requested and is deemed proper.

The disclosure has been objected to because of informalities. Applicant has now addressed this issue with the proposed amendment to the specification. Applicant wishes to thank the Examiner for the helpful comment and the suggestion.

Claims 1-3, 5-12, 23 and 25 have been rejected as being obvious based on Chaffin, III et al. (U.S. 3,831,006) in view of Knepple et al. (WO 99/41014).

It is Applicant's position that each of independent claims 1, 10 and 23 highlight a combination of features including the feature that the various containers have markings with a unique identification wherein these markings are applied prior to the time of receiving a sample in the container. This limitation is important both with regard to the method and system wherein all containers in the system have a unique identifier as well as the feature that the identification is associated with the container from effectively its initial existence (from prior to any normal use as a container). The unique identifier is important as this entails that there is a universe of such containers and no container has or can have the same identifier. This is for example similar to network components where there are unique "MAC" addresses.

This is different from a random number wherein two random number generators could in fact produce the same number, particularly if the numbers are generated at two different system locations as noted in the previous response with regard to Chaffin, III et al. In any event, it is clear that Chaffin, III et al. is missing one or both of the claimed features (depending upon the interpretation with regard to the unique identification code of the invention and the random numbers generated according to Chaffin, III et al.). In any event, it can be agreed that Chaffin, III et al. does not teach each and every feature as specified and required by independent claims 1, 10, 23 and 25.

It can be agreed that Knepple et al. discloses identification labels 12 applied during production of the container 10. The motivation and direction of this teaching as to the person of ordinary skill in the art relates to providing the label such that it is not a contaminant or will not cause problems with regard to later analysis. The production process takes this into account such that later use of the container will not cause problems as noted.

It is applicant's position that based on the teachings of these references, there is no suggestion to provide the combination of features as claimed. Specifically, considering Applicant's invention and considering the random numbers generated according to Chaffin, III et al. and the identifiers provided at production according to Knepple et al., one may be lead to the conclusion that Chaffin, III et al. could be modified to a system and method with preapplied labels. However, this is a hindsight approach, namely considering Applicant's invention and selecting individual teachings from the two references. However, considering the references fairly, for what they teach, the references do not suggest the combination as

proposed. Further, to use a prelabeled test tube as suggested by Knepple et al. in a system as designed by Chaffin, III et al. would not be possible and would require a complete redesign of the Chaffin, III et al. system, as explained clearly below.

The specification of Chaffin III et al is very clear in describing the following concepts:

A patient enters the hospital and is give a unique random number x selected from a first set of random numbers X (see col.3, lines 1-5);

Random number x and patient data are stored (col.3, lines 12-14);

A technician takes several sample containers 15 and several labels 16. Each label is encoded with a unique random number y selected from a second set of random numbers Y (see col.3, lines 25-30);

Sample transfer station 22 divides the sample into sub-samples and transfers the sub-samples to various containers 23. Each container receives a label encoded with a random number z selected from a group of random numbers Z (see col.3, lines 50-55);

Each sub-sample can be split again with a similar procedure.

It is therefore necessary for the system to operate to have separate (nonoverlapping) groups of numbers X , Y , Z . A number is selected from one of these groups according to a precisely defined logic. The Number applied to a given container provides an indication as to the level of splitting of the sample, i.e. if the sample thus labelled is obtained by the first, second or subsequent splitting step.

The enclosed sketch (Attachment A) gives a visual idea of this concept. In the enclosed sketch we have assumed by way of example that:

Group X contains the numbers in the range 1001-2000;

Group Y contains the numbers in the range 2001-3000;

Group Z contains the numbers in the range from 3001-4000.

Furthermore the patient entering the hospital is given random number $x = 1354$;

The first test tube or container is given number $y = 2016$;

The content of the test tube is split and a sub-sample is introduced into a sub-container receiving random number $z = 3980$.

During processing, the system is able to recognize that the sub-container resulted from a first level of splitting because it has been assigned a number belonging to the range 3001-4000.

Were the test-tubes labelled at the production stage, as suggested by the secondary reference, they would not be usable in a system designed as discussed by Chaffin III et al.

Indeed, it is quite evident that were the containers pre-labelled, i.e. provided with numbers which are not selected from special (non-overlapping) groups of numbers, the entire system would not operate at all.

It is an essential condition for the Chaffin, III et al. system to work that the random number assigned to the test tube or the sub-container be generated from a special group of numbers (X, Y or Z) at the very moment in which the test tube or the sub-container receives its sample. This rules out the possibility of using the teaching of Knepple et al. in the Chaffin, III et al. system.

Since a combination of Chaffin, III et al. and Knepple et al., is not obvious and indeed

impossible, the teachings as a whole fail to suggest the features claimed in claims 1, 10, 23 and 25.

According, Knepple et al. does not provide any motivation to depart from the arrangement of Chaffin, III et al. A fair reading of Chaffin, III et al. leads one of ordinary skill in the art to realize that the Chaffin, III et al. method and system are not compatible with a system with containers having preapplied numbers. Basically, the consideration of the Knepple et al. preapplied numbers and Chaffin, III et al. would at least require a complete abandonment of the Chaffin, III et al. system. As such, the reference does not provide teachings in combination with Knepple et al. to lead or motivate the person of ordinary skill in the art toward the combination of features claimed. Further, Knepple et al. fails to suggest the features of the invention. Absent references which present clear teachings with motivations to provide each element arranged as specified in the claims, the combination of features should be considered novel and unobvious.

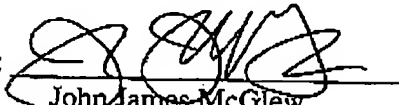
Claims 21, 22, 24 and 26-28 have been rejected as obvious based on Chaffin, III et al., Knepple et al. and Carr et al. However, for the same reasons as noted above, the referenced fail to suggest the invention as claimed. Reconsideration of the rejections is requested.

Applicant respectfully requests that the Examiner consider the above and allow Applicant's representative to discuss the claims as now presented with regard to the prior art and the outstanding rejections. It is hoped that a telephone interview would occur in early July.

Favorable action on the merits is requested.

Respectfully submitted
For Applicant,

By:


John James McGlew
Reg. No. 31,903

JJM:jms

Enclosed: Attachment A
70479.14

DATED: July 2, 2004
SCARBOROUGH STATION
SCARBOROUGH, NEW YORK 10510-0827
(914) 941-5600

SHOULD ANY OTHER FEE BE REQUIRED, THE PATENT AND TRADEMARK OFFICE
IS HEREBY REQUESTED TO CHARGE SUCH FEE TO OUR DEPOSIT ACCOUNT 13-
0410.